IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

GARY BRYAN BRACKIN, individually and in his capacity as Surviving Spouse of PAMELA W. BRACKIN, Deceased, **Plaintiff,** **v.** **MEDTRONIC, INC., et al.,** **Defendants.**	**Case No. 2:17-cv-2101**

DEFENDANTS MEDTRONIC, INC.'S AND MEDTRONIC MINIMED, INC.'S REPLY BRIEF IN SUPPORT OF MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF WILLIAM J. VIGILANTE, JR., PH.D, CPE

Defendants Medtronic, Inc. and Medtronic MiniMed, Inc. ("Medtronic Defendants"), submit this Reply Brief in Support of Motion to Exclude Opinions and Testimony of William J. Vigilante, Jr., Ph.D, CPE ("Dr. Vigilante"), showing the Court as follows:

I. BACKGROUND

The Medtronic Defendants deposed Plaintiff's human factors and warnings expert Dr. Vigilante on September 14, 2018. (Doc. 134-3 at 2). That same day, the Medtronic Defendants filed a Motion to Exclude the opinions and testimony of Dr. Vigilante, and a memorandum of law in support of said motion, arguing: (1) that Dr. Vigilante was not qualified to offer any labeling, warnings, or human factors opinions about FDA regulated medical devices or any engineering or design opinions about FDA regulated medical devices; (2) that Dr. Vigilante was not qualified to offer any opinions about medical causation; and (3) that Dr. Vigilante should be precluded from offering any causation opinions or testifying about causation issues because his opinions are based on unsubstantiated, unreliable assumptions. (Docs. 124, 124-1, at 10-17). Plaintiff responded in

opposition on September 28, 2018, arguing (1) that Dr. Vigilante is qualified to offer opinions on human factors in this case; and (2) that Dr. Vigilante applied a reliable methodology and his opinions in this case are reliable. (Doc. 134 at 8-16) ("Plaintiff's Response"). The deposition transcript[1] of Dr. Vigilante, which was not available when the Medtronic Defendants filed their Motion, has only fortified the arguments previously made based on his report and prior testimony, and his testimony must be excluded.[2] He has now conceded his lack of expertise in warnings and labeling in FDA-approved medical devices as well as the regulations that govern those warnings and labeling. Further, he has now conceded he has not evaluated whether a temporary blocked vent occurred with respect to Ms. Brackin, therefore he cannot provide any causation opinion and his opinions on temporary blocked vent are thus speculative and unreliable.

II. ARGUMENT

A. PLAINTIFF'S RESPONSE SHOWS DR. VIGILANTE IS NOT QUALIFIED TO OFFER OPINIONS ON HUMAN FACTORS ANALYSIS IN THIS CASE

Plaintiff claims that Dr. Vigilante is broadly qualified to offer opinions on "any product which will interact in one way or another with human beings." (Plaintiff's Response at 10). Dr. Vigilante places no limits whatsoever on his ability to apply human factors principles to analyzing a product, be it a medical device, a vehicle, workplace equipment, or a consumer product. (Doc. 134-3 at 176:12-16; 21-23). To try and support this broad claim of expertise, Plaintiff cites to *In*

[1] A true and correct copy of the September 14, 2018, Vigilante Deposition is attached as **Exhibit A**.

[2] Plaintiff's Response does not address in any fashion the Medtronic Defendants' argument that Dr. Vigilante should be excluded from offering any opinions on medical causation. (*See* Doc. 124-1 at 13-14; *see generally* Plaintiff's Response). Accordingly, for the reasons previously stated in the Medtronic Defendants' Memorandum of Law, to the extent the Court permits Dr. Vigilante to offer any expert opinions or testimony in this matter, he should be excluded from testifying or offering any opinions on the medical cause of Mrs. Brackin's injuries and death.

re Yamaha Motor Corp. Rhino ATV Prod. Liab. Litig., 816 F. Supp. 2d 442 (W.D. Ky. 2016) (hereafter, "*Yamaha*"). However, *Yamaha* demonstrates why Dr. Vigilante's experience is not applicable to a Class III, FDA regulated device like the Medtronic MiniMed Paradigm® MMT-523 insulin pump ("Pump"). The *Yamaha* defendants argued that an engineering "design process" expert only had expertise with the automobile industry, not the off-road vehicles at issue in the case. *Id.* at 452. The district court rejected this argument, concluding that the processes the expert utilized were not unique to the automotive industry, and that the design standards he described "could be applied to products ranging from ATVs to toasters." *Id.*

Here, Dr. Vigilante is not applying general engineering principles or looking at global standards. He purports to comment on the specific design and use of a type of product with which he has no familiarity. Aside from the obvious rational basis for comparing design principles between automobiles and off-road vehicles, the *Yamaha* court noted that while the automotive expert was certified in and relied on industry-specific standards, the specific standards incorporated global standards that could be applied to the related off-road industry. Dr. Vigilante, on the other hand, intends to comment on whether highly-scrutinized warnings governed by FDA regulations are adequate, despite being completely unfamiliar with these governing regulations. The *Yamaha* court found that the challenged expert was qualified to testify about DFMEA[3] because this standard was used by engineers across industries to test for potential issues with new product designs, 816 F. Supp. 2d at 451 & n.2, but here Dr. Vigilante did not conduct a full DFMEA for the Pump, and he has never done so for a medical device, (134-3 at 177:11-25, 178:1-18). At his deposition, Dr. Vigilante acknowledged that he did not examine or handle the specific Pump at issue, nor did he examine an exemplar of the Pump in forming his opinions for this case.

[3] "Design Failure Mode and Effects Analysis."

(Doc. 134-3 at 18:6-16, 19:2-15). His broad consulting experience covers many product types, but he has never done consulting for any medical device companies or for the FDA. (*Id.* at 37:10-15, 42:14-24). He has never worked for a medical device company or at the FDA. (*Id.* at 42:9-13). He has never prepared warnings for a medical device or evaluated warnings for either a medical device company or the FDA. (*Id.* at 43:2-17). He has never been involved in the design process for a medical device or performed a risk analysis on behalf of a medical device company. (*Id.* at 45:15-25). He disclaims any expertise on FDA regulations or regulatory submissions. (*Id.* at 48:10-20). He can offer no on opinions on whether the allegedly inadequate labeling of the Pump complied with FDA requirements. (*Id.* at 50:8-14). He has never designed a medical device and cannot offer any opinions as to an alternative design for the Pump. (*Id.* at 54:25, 55:1-10). His evaluation in this case marks only the second time in his entire career Dr. Vigilante has analyzed the labeling or performed a risk analysis of a medical device, and the sole other instance was also on behalf of a plaintiff in the course of litigation. (*Id.* at 46:3-9). The Sixth Circuit "has recognized for some time that expert testimony prepared solely for purposes of litigation, as opposed to testimony flowing naturally from an expert's line of scientific research or technical work, should be viewed with some caution." *Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426, 434 (6th Cir. 2007).

Dr. Vigilante may be qualified to comment on human factors in the abstract, but he has provided no foundation for his ability to answer the specific questions in this case about human factors analysis as applied to medical devices. *See Anglefix, LLC v. Wright Med. Tech., Inc.*, No. 13-CV-2407-JPMTMP, 2017 WL 2973989, at *6 (W.D. Tenn. July 12, 2017) ("The issue with regard to expert testimony is not the qualifications of a witness in the abstract, but whether those qualifications provide a foundation for a witness to answer a specific question."). For these reasons, the Court should exclude Dr. Vigilante's expert opinions in this case.

B. REITERATING DR. VIGILANTE'S EXPERT REPORT DOES NOT JUSTIFY PERMITTING HIM TO OFFER THE OPINIONS CONTAINED THEREIN

Plaintiff's Response contains a long reiteration of sections from Dr. Vigilante's expert report. (Plaintiff's Response at 10-16). Citing to no caselaw or other authorities, Plaintiff then concludes that Dr. Vigilante "applied standard human factors methodologies applicable to any product design to reach a reliable conclusion that Medtronic's product was defective in design and for failure to warn" in concluding that the Pump was a "defective product" which "created a unreasonably dangerous condition that caused or contributed to Pamela Brackin's injury and death." (*Id.* at 16). However, Dr. Vigilante's opinions are not the product of a reliable methodology because, regardless of how arrived at, the basis for every conclusion in Dr. Vigilante's expert report is the unsubstantiated assumption that a temporary blocked vent caused a malfunction which led to an overdose of insulin:

> Q. Okay. That's helpful. So it was not part of your analysis to determine whether or not there was a temporary blocked vent that actually occurred here?
> A. [DR. VIGILANTE] It was my understanding it was an assumption I used to link the causation.
> Q. Understood. But it wasn't your analysis to determine whether or not there was a temporary blocked vent that actually occurred?
> A. That's correct, I did not set out or was asked to determine that.

(Doc. 134-3 at 83:3-14). This assumption renders his causation opinions unreliable. *See Lozar v. Birds Eye Foods, Inc.*, 529 F. App'x 527, 530 (6th Cir. 2013) ("To be reliable, the opinion must not have 'too great an analytical gap between the expert's conclusion, on the one hand, and the data that allegedly supports it, on the other." (quoting *Tamraz*, 620 F.3d at 675-76)); *see also Davison v. Cole Sewell Corp.*, 231 F. App'x 444, 449 (6th Cir. 2007) (holding plaintiff's expert's opinions were legally insufficient because he failed to identify the cause of the alleged injury with a sufficient degree of certainty). Accordingly, all of Dr. Vigilante's causation opinions and testimony should be excluded.

Dated: October 17, 2018

GREENBERG TRAURIG, LLP

/s/ R. Clifton Merrell
Lori G. Cohen
Georgia Bar No. 174455
(Admitted *Pro Hac Vice*)
R. Clifton Merrell
Georgia Bar No. 593903
(Admitted *Pro Hac Vice*)
Jessica Cabral Odom
Georgia Bar No. 140935
(Admitted *Pro Hac Vice*)
GREENBERG TRAURIG, LLP
Terminus 200
3333 Piedmont Road, N.E.
Suite 2500
Atlanta, GA 30305
Telephone: (678) 553-2100
Facsimile: (678) 553-2212
cohenl@gtlaw.com
merrellc@gtlaw.com
odomj@gtlaw.com

Quinn Carlson (TN Bar # 25603)
J. Carter Thompson (TN #35494)
BAKER, DONELSON, BEARMAN,
CALDWELL & BERKOWITZ, P.C.
165 Madison Avenue, Suite 2000
Memphis, Tennessee 38103
Telephone: (901) 526-2000
Facsimile: (901) 577-2303
qcarlson@bakerdonelson.com

Counsel for Defendants Medtronic, Inc. and Medtronic MiniMed, Inc.

CERTIFICATE OF SERVICE

This is to certify that I have this day served a copy of the within and foregoing **DEFENDANTS MEDTRONIC, INC.'S AND MEDTRONIC MINIMED, INC.'S REPLY BRIEF IN SUPPORT OF MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF WILLIAM J. VIGILANTE, JR., PH.D, CPE** via electronic mail and via first class United States Mail to all counsel of record as follows:

Gary K. Smith
Philip M. Campbell
Gary K. Smith Law Firm, PLLC
1770 Kirby Parkway, Suite 427
Memphis, Tennessee 38138
gsmith@garyksmithlaw.com

Kevin Haverty
Williams Cedar LLC
1515 Market Street, Suite 1300
Philadelphia, PA 19102
khaverty@williamscedar.com

Marlene J. Goldenberg
GoldenbergLaw, PLLC
800 LaSalle Avenue, Suite 2150
Minneapolis, MN 55402
mjgoldenberg@goldenberglaw.com

This 17th day of October, 2018.

/s/ R. Clifton Merrell
R. Clifton Merrell
GREENBERG TRAURIG, LLP
Terminus 200
3333 Piedmont Road NE, Suite 2500
Atlanta, Georgia 30305
(678) 553-2100
(678) 553-2386 (facsimile)
merrellc@gtlaw.com

Attorney for Defendants Medtronic, Inc. and Medtronic MiniMed, Inc.